

SERIAL NO. 10/034694

PATENT

REMARKS

As of the Office Action dated July 14, 2003, claims 1-29 are pending in the present application, with claims 1-15, 19-21, 23-26 and 29 having been rejected, and claims 16-18, 22, 27 and 28 having been objected to. The rejection is traversed.

Status of the Formal Drawings

The examiner objected to the drawings as originally filed as being informal, and required formal drawings to be filed in reply to the Office action. Applicants have forwarded formal drawings by Express Mail, concurrently with the filing of this Reply.

Status of Examiner's Consideration of Applicants' Information Disclosure Statements

The examiner's acknowledgement of applicants' Information Disclosure Statement filed September 17, 2002, is noted with appreciation.

Explanation of the Amendment

Claim 5 has been amended to provide a sufficient antecedent basis for the term "the commissure posts" as required by the examiner.

Claim 15 As Amended Is Not Indefinite under 35 U.S.C. § 112

Claim 5 was rejected under 35 U.S.C. § 112 as lacking sufficient antecedent basis for the term "the commissure posts" in line 1. The claim has been amended to furnish the required antecedent basis. Withdrawal of the rejection is respectfully requested.

*Claims 1-4, 6-7, 9-10, 14-15, 23 and 26 are not Anticipated
by Goldstein et al. Under 35 U.S.C. § 102(b)*

Claims 1-4, 6-7, 9-10, 14-15, 23 and 26 were rejected under 35 U.S.C. § 102(b) as being anticipated by US Patent No. 5,899,937 issued to Goldstein et al. The rejection is traversed.

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Goldstein et al. pertains to a pulsatile flow system for developing heart valves in which the heart valves open fully upon application of fluid pressure in a forward direction. According Goldstein et al. "the first phase is to study the cellular activity of a *normal, living porcine aortic valve* under physiologic conditions in an in vitro flow loop," column 9, lines 50-52; see also column 13, lines 38-40; column 15, lines 44-67. A normal living valve would be expected to be fully open upon application of fluid pressure in the forward direction.

In support of the rejection, the examiner cites to Fig. 2 and column 10, lines 44-47 of Goldstein et al. Observing that the nozzle in Fig. 2 has a trapezoidal shape, the examiner asserts that Goldstein et al. must teach a valve that is not fully opened. This is incorrect. In fact, Fig. 2 itself contains the legend "FULLY OPEN LEAFLETS" just above the nozzle, leaving no doubt that the nozzle represents fully open leaflets. Moreover, the portion of the specification at column 7, lines 44-47 cited by the examiner explicitly states that "the leaflets are in a full open position along the sides of the nozzle." If the leaflets are thought of as being comparable to the flexible membrane, clearly the disclosure of Goldstein et al. that the leaflets are in a full open position cannot possibly anticipate the limitation that a "flexible membrane does not fully open upon application of fluid pressure in a forward direction" (claim 1) or that a "flexible membrane ... does not fully open in response to fluid pressure in a forward direction" (claim 23). The rejection must be withdrawn.

It will be appreciated that the reason for the trapezoidal shape of the nozzle in Fig. 2 of Goldstein et al. has nothing to do with the leaflets being less than fully opened. The reason is to simulate a stented valve by tapering the flow field as a nozzle, see column 7, lines 32-42. However, the leaflets themselves are in a fully open position along the sides of the nozzle; id. lines 42-43.

*Claim 29 is not Anticipated
by Goldstein et al. Under 35 U.S.C. § 102(e)*

Claim 29 was rejected under 35 U.S.C. § 102(e) as being anticipated by US Patent No. 6,562,069 issued to Cai et al. The rejection is traversed.

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Without prejudice to later overcoming the rejection in the manner suggested by the examiner, applicants believe that claim 29 is distinguishable over the disclosure of Cai et al. Since the examiner has not cited any specific material in Cai et al. to support the rejection, applicants shall respond as well as possible to the rejection in the interests of advancing the prosecution.

Cai et al. pertains to polymer leaflet designs for medical devices. Such leaflets would be expected to be fully open upon application of fluid pressure in a forward direction. While applicants do not know the technical basis of the examiner's rejection, applicants observe that the Cai et al. embodiments have leaflets that *when in their relaxed states* are open in varying degrees, i.e. not fully opened. However, regardless of the relaxed states of these leaflets, they can be expected to be fully opened upon application of fluid pressure in a forward direction. Since claim 29 includes the limitation that the "flexible membrane ... opens no more than about 80 percent ... upon application of fluid pressure in a forward direction," it cannot be anticipated by Cai et al. Withdrawal of the rejection respectfully is requested.

*Claims 5, 8, 11-13, 19-21 and 24-25
are not Unpatentable Under 35 U.S.C. § 103*

Claims 5, 11-13, 19-21 and 25 were rejected under 35 U.S.C. § 103 as being obvious over Goldstein et al. in view of US Patent No. 4,778,461 issued to Pietsch et al. The rejection is traversed. As these claims are dependent from either claim 1 or claim 23, applicants will address the non-obviousness of claims 1 and 23, it being understood that dependent claims 5, 11-13, 19-21 and 25 are considered to include the limitations of claims 1 or 23, and therefore would be patentable if claims 1 and 23 are patentable. While these dependent claims may contain additional limitations of independent patentable significance, discussion thereof at this time would be superfluous.

The disclosure of Goldstein et al. is discussed above. The examiner asserts that Pietsch et al. disclosures a heart valve stent with commissure posts and having a membrane of polyurethane or silicon integrally cast with the stent. However, this disclosure does not teach leaflets less than fully open, so that the combination of

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Goldstein et al. and Pietsch et al. still only discloses leaflets that are in a full open position. Since Goldstein et al. in view of Pietsch et al. contains absolutely no teaching or suggestion that a "flexible membrane does not fully open upon application of fluid pressure in a forward direction" (claim 1) or that a "flexible membrane ... does not fully open in response to fluid pressure in a forward direction" (claim 23), the independent claims and their dependent claims are not obvious. The rejection must be withdrawn.

Claims 8 and 24 were rejected under 35 U.S.C. § 103 as being obvious over Goldstein et al. in view of US Patent No. 5,176,153 issued to Eberhardt et al. The rejection is traversed since claims 1 and 23 from which they depend are not obvious, for the reasons explained above as supplemented in the following paragraph. While these dependent claims may contain additional limitations of independent patentable significance, discussion thereof at this time would be superfluous.

The rejection of claims 8 and 24 uses the Eberhardt et al. reference instead of the Pietsch et al. reference. The examiner asserts that Eberhardt et al. discloses the use of certain test frequencies. However, this disclosure does not teach leaflets less than fully open, so that the combination of Goldstein et al. and Eberhardt et al. still only discloses leaflets that are in a full open position. Since Goldstein et al. in view of Eberhardt et al. contains absolutely no teaching or suggestion that a "flexible membrane does not fully open upon application of fluid pressure in a forward direction" (claim 1) or that a "flexible membrane ... does not fully open in response to fluid pressure in a forward direction" (claim 23), the independent claims and their dependent claims are not obvious. The rejection must be withdrawn.

Conclusion

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and the timely issuance of a Notice of Allowance. If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned at (952) 253-4135.

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Michele Read

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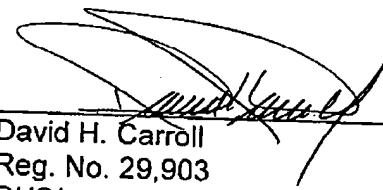
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Respectfully submitted,

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Date: October 14, 2003



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